

**PROPOSED AMENDMENTS TO
A-ENGROSSED HOUSE BILL 4110**

1 On page 1 of the printed A-engrossed bill, line 2, before the period insert
2 “; creating new provisions; and amending ORS 689.522”.

3 On page 2, after line 14, insert:

4 **“SECTION 3.** ORS 689.522 is amended to read:

5 “689.522. (1) As used in this section:

6 “(a) ‘Biological product’ means, with respect to the prevention, treatment
7 or cure of a disease or condition of human beings, a virus, therapeutic serum,
8 toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic
9 product, protein other than a chemically synthesized polypeptide, analogous
10 products or arsphenamine or any other trivalent organic arsenic compound.

11 “(b) ‘Biosimilar product’ means a biological product [*licensed by*] **that** the
12 United States Food and Drug Administration, **relying on a reference bi-**
13 **ological product:**

14 **“(A) Licensed** pursuant to 42 U.S.C. 262(k)(3)(A)(i); **or**

15 **“(B) Approved based on an application filed under 21 U.S.C.**
16 **355(b)(2).**

17 “(c) ‘Interchangeable’ means[,]:

18 **“(A) In reference to a biological product, that the United States Food and**
19 **Drug Administration has determined that a biosimilar product meets the**
20 **safety standards set forth in 42 U.S.C. 262(k)(4); or**

21 **“(B) In reference to a biological product described in paragraph**
22 **(b)(B) of this subsection, that the United States Food and Drug Ad-**

1 **ministration has designated the product as therapeutically equivalent**
2 **in the list of approved drug products with therapeutic evaluations.**

3 “(d) ‘Reference biological product’ means the biological product licensed
4 pursuant to 42 U.S.C. 262(a) **or approved based on an application filed**
5 **under 21 U.S.C. 355(b)(1)** against which a biological product is evaluated
6 in an application submitted to the United States Food and Drug Adminis-
7 tration for licensure **or approval** of a biological product as a biosimilar
8 product or for determination that a biosimilar product is interchangeable.

9 “(2) A pharmacy or pharmacist filling a prescription order for a biological
10 product may not substitute a biosimilar product for the prescribed biological
11 product unless:

12 “(a) The biosimilar product has been determined by the United States
13 Food and Drug Administration to be interchangeable with the prescribed
14 biological product;

15 “(b) The prescribing practitioner has not designated on the prescription
16 that substitution is prohibited;

17 “(c) The patient for whom the biological product is prescribed is informed
18 of the substitution prior to dispensing the biosimilar product;

19 “(d) The pharmacy or pharmacist provides written, electronic or tele-
20 phonic notification of the substitution to the prescribing practitioner or the
21 prescribing practitioner’s staff within three business days of dispensing the
22 biosimilar product; and

23 “(e) The pharmacy or pharmacist retains a record of the substitution for
24 a period of not less than three years.

25 “(3) The State Board of Pharmacy shall post and regularly update on a
26 website maintained by the board a list of biosimilar products determined by
27 the United States Food and Drug Administration to be interchangeable.

28 **“SECTION 4.** ORS 689.522, as amended by section 4, chapter 342, Oregon
29 Laws 2013, is amended to read:

30 “689.522. (1) As used in this section:

1 “(a) ‘Biological product’ means, with respect to the prevention, treatment
2 or cure of a disease or condition of human beings, a virus, therapeutic serum,
3 toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic
4 product, protein other than a chemically synthesized polypeptide, analogous
5 products or arsphenamine or any other trivalent organic arsenic compound.

6 “(b) ‘Biosimilar product’ means a biological product [*licensed by*] **that** the
7 United States Food and Drug Administration, **relying on a reference bi-**
8 **ological product:**

9 “(A) **Licensed** pursuant to 42 U.S.C. 262(k)(3)(A)(i); **or**

10 “(B) **Approved based on an application filed under 21 U.S.C.**
11 **355(b)(2).**

12 “(c) ‘Interchangeable’ means[,]:

13 “(A) In reference to a biological product, that the United States Food and
14 Drug Administration has determined that a biosimilar product meets the
15 safety standards set forth in 42 U.S.C. 262(k)(4); **or**

16 “(B) **In reference to a biological product described in paragraph**
17 **(b)(B) of this subsection, that the United States Food and Drug Ad-**
18 **ministration has designated the product as therapeutically equivalent**
19 **in the list of approved drug products with therapeutic evaluations.**

20 “(d) ‘Reference biological product’ means the biological product licensed
21 pursuant to 42 U.S.C. 262(a) **or approved based on an application filed**
22 **under 21 U.S.C. 355(b)(1)** against which a biological product is evaluated
23 in an application submitted to the United States Food and Drug Adminis-
24 tration for licensure **or approval** of a biological product as a biosimilar
25 product or for determination that a biosimilar product is interchangeable.

26 “(2) A pharmacy or pharmacist filling a prescription order for a biological
27 product may not substitute a biosimilar product for the prescribed biological
28 product unless:

29 “(a) The biosimilar product has been determined by the United States
30 Food and Drug Administration to be interchangeable with the prescribed

1 biological product;

2 “(b) The prescribing practitioner has not designated on the prescription
3 that substitution is prohibited;

4 “(c) The patient for whom the biological product is prescribed is informed
5 of the substitution prior to dispensing the biosimilar product; and

6 “(d) The pharmacy or pharmacist retains a record of the substitution for
7 a period of not less than three years.

8 “(3) The State Board of Pharmacy shall post and regularly update on a
9 website maintained by the board a list of biosimilar products determined by
10 the United States Food and Drug Administration to be interchangeable.”.

11 In line 15, delete “3” and insert “5”.

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